1654

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/008,722 Confirmation No. 5741
Applicant : AOKI et al.
Filed : December 6, 2001
Title : METHODS FOR TREATING A MUCUS SECRETION

TC/A.U. : 1600/1654
Examiner : GUPTA, A.

Docket No. : 16952CON1DIV5CIP; D2851CON1DIV5CIP
Customer No. : 33197

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June 16, 2004
Janet McGhee

Mail Stop AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO FEBRUARY 24, 2004 OFFICE ACTION AND

PETITION FOR ONE MONTH EXTENSION OF TIME

Sir:

This response is being submitted in reply to the Office Action of February 24, 2004. A response was due May 24, 2004. Applicant hereby petitions for a one-month extension of time. A response with a one-month extension of time is due June 24, 2004. A check in the amount of $110.00 is enclosed for the petition fee for a one-month extension of time. Accordingly, this response is being timely filed. In response to the Office Action, please consider the following remarks:

Remarks/Arguments begin on page 2 of this paper.

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Remarks

Claims 1-16 are currently pending.

Rejections Based On Estoppel Under 37 CFR 1.658(c)

Claims 1-16 have been rejected on the grounds of estoppel under 37 CFR 1.658(c). Applicant traverses this rejection.

The rejection appears to be based on the Examiner's opinion that because one of the symptoms associated with otitis media is excessive mucus secretion in the respiratory tract and behind the eardrum, that claim 5 of Sanders et al. (U.S. Patent No. 5,766,605; hereinafter Sanders) directed to treatment of otitis media by transtympanic injection of botulinum toxin reads on the treatment of a mucus secretion that is not a symptom of rhinorrhea. The Examiner contends that Sanders discloses a claim or suggests the treatment of a non-rhinorrhea mucus secretion, and therefore, that claim 5 of Sanders could have been the basis of an additional count under 37 CFR 1.633(e)(1).

Applicant respectfully disagrees that the subject matter of the present claims could have been presented during the interference. Applicant submits that the present claims are not identical with claim 5 of Sanders and are not obvious variants of claim 5 of Sanders.

Otitis media is associated with many symptoms, only one of which may be mucus secretion. Claim 5 of Sanders is directed to the treatment of otitis media, and is not directed to or even suggestive of reducing or treating any specific symptom of

otitis media, let alone to treating mucus secretion. Thus, the subject matters of claim 5 of Sanders and the present claims are distinct and different, one from the other. Put another way, claim 5 of Sanders does not even suggest the present claims 1 to 16.

In addition, because Sanders does not provide any disclosure, teaching, or suggestion about treating any specific symptom of otitis media by the administration of botulinum toxin, applicant submits that the subject matter of the present claims is not obvious in view of Sanders, including claim 5 of Sanders. Sanders fails to provide any disclosure, teaching, or suggestion, as to the type of symptom of otitis media that may be treated by transtympanic administration of botulinum toxin. Importantly, Sanders does not even suggest that non-rhinorrhea mucus secretion can be treated using botulinum toxin, as recited in the present claims.

In view of the above, applicant submits that none of the present claims 1 to 16 could have been properly added to the interference, and that the estoppel rejection under 37 CFR 1.658(c) has been overcome.

Rejection Under 35 U.S.C. § 102

Claims 1-16 have been rejected under 35 U.S.C. § 102(g) as allegedly being anticipated by Sanders. Claims 1-16 have also been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Sanders and TOS (HNO).

Applicant respectfully traverses the rejections.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (Emphasis added; *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). An anticipating reference must describe the patented subject matter with sufficient clarity and detail to establish that the subject matter existed and that its existence was recognized by persons of ordinary skill in the art (*ATD Corp. v. Lydall, Inc.*, 48 USPQ 2d 1321, 1328 (Fed. Cir. 1998)).

First, applicant submits that the rejection under 35 U.S.C. § 102(b) regarding Sanders and TOS is improper. In order for a claim to be properly rejected under 35 U.S.C. § 102, each and every element as set forth in the claim must be described in a single prior art reference. The rejection under § 102(b) involves two references. Therefore, applicant submits that this rejection under 35 U.S.C. § 102(b) is improper and respectfully requests the Examiner to withdraw this rejection.

Nevertheless, applicant submits that the present claims are not anticipated by Sanders, or the combination of Sanders and TOS. For example, neither Sanders, nor the combination of Sanders and TOS, discloses, teaches, or suggests the present invention. Neither Sanders nor TOS discloses, teaches, or even suggests administering a botulinum toxin, such as a botulinum toxin type A, to a patient to reduce a mucus secretion, which is not a symptom of rhinorrhea, as recited in claims 1 to 7. Furthermore, neither of the references discloses, teaches, or even suggests administering a botulinum toxin to a mucus

secreting gland to treat a mucus secretion that is not a symptom of rhinorrhea, as recited in claims 8 to 15. Similarly, the references do not disclose, teach, or even suggest injecting an excessively secreting, cholinergic nervous system influenced gland or local mucus gland area of a human patient with a botulinum toxin type A to reduce an excessive mucus gland secretion that is not a symptom of rhinorrhea, as recited in claim 16.

Sanders mentions that botulinum toxin may be used to treat otitis media by transtympanic injection (column 2, lines 39-40; column 10, lines 41-42; and column 12, lines 3-5). The Examiner believes that this disclosure anticipates the present claims directed to reducing or treating mucus secretions that are not a symptom of rhinorrhea.

Applicant vigorously disagrees. For example, as acknowledged by the Office Action (page 4, third full paragraph), excessive mucus secretion is only one of many symptoms associated with otitis media. Some other symptoms of otitis media include pain, fever, hearing loss, sense of fullness in the ear, vomiting, and tinnitus. In addition, there are three main types of otitis media: (i) acute otitis media; (ii) chronic otitis media; and (iii) otitis media with effusion.

Applicant submits that a general disclosure of treating otitis media, as set forth in Sanders, does not provide even a suggestion, let alone a clear and detailed description, that the administration of botulinum toxin is useful to treat any symptom of otitis media, let alone treating a mucus secretion associated with otitis media. The references, that is Sanders and TOS, do

not describe the claimed subject matter with clarity and detail, which is required to properly support a rejection under 35 U.S.C. § 102 (*ATD Corp. v. Lydall, Inc.*, supra).

The disclosure of Sanders for a treatment for otitis media by transtympanically administering botulinum toxin to a patient does not disclose, teach, or even suggest that the administration of a botulinum toxin reduced mucus secretions associated with otitis media. This is particularly true since mucus secretion is only one symptom among many different symptoms associated with otitis media.

Applicant submits that Sander's disclosure of a treatment for otitis media constitutes nothing more than speculation of potential treatment and is not a "description" of the claimed invention within the meaning of 35 U.S.C. § 102 (*In re Wiggins*, 179 USPQ 421 (CCPA 1973)). Simply put, the brief mention in Sanders of treating otitis media is insufficient for Sanders to anticipate the presently rejected claims. Therefore, applicant submits that Sanders, and Sanders and TOS, do not anticipate the presently rejected claims (*Air Products and Chemicals v. Chas. S. Tanner*, 219 USPQ 223 1983).

In view of the above, applicant submits that the present claims, and claims 1-16 in particular, are not anticipated by Sanders under 35 U.S.C. § 102(g), or by Sanders and TOS under 35 U.S.C. § 102(b). In addition, applicant submits that the present claims are unobvious from and patentable over Sanders, or the combination of Sanders and TOS, under 35 U.S.C. § 103.

Each of the present dependent claims is separately patentable over the prior art. For example, none of the prior art disclose, teach, or even suggest the present methods including the additional feature or features recited in any of the present dependent claims. Therefore, applicant submits that each of the present claims is separately patentable over the prior art.

In conclusion, applicant has shown that the present claims are not anticipated by and are unobvious from and patentable over the prior art under 35 U.S.C. §§ 102 and 103. Therefore, applicant submits that the present claims, that is claims 1-16 are allowable. Therefore, applicant respectfully requests the Examiner to pass the above-identified application to issuance at an early date. Should any matters remain unresolved, the Examiner is requested to call (collect) applicant's attorney at the telephone number given below.

Respectfully submitted,

Date: June 16, 2004

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